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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,791	12/21/2005	Dong Hyun Kim	008483.P001	4525

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EXAMINER	
CHEN, CATHERYNE	
ART UNIT	**PAPER NUMBER**
1655	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,791	KIM ET AL.	
	Examiner	Art Unit	
	CATHERYNE CHEN	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *11 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *May 26, 2005.*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Currently, Claims 1-12 are pending. Claims 1-10 are examined on the merits.

Election/Restrictions

Applicant's election without traverse of the species compound K, gesenoside Rh1, Rh2, and delta 20-ginsenoside Rh2, bifidobacterium cholerium KK-1, in the reply filed on Aug. 11, 2008 is acknowledged.

Claims 11-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on Aug. 11, 2008.

Claim Objections

Claim 3 is objected to because of the following informalities:

A space is required between "compound K" and "(20-O-beta-D-glucopyranocyl-20(S)-protopanaxadiol)." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 2, the term “high” temperature is indefinite because one does not know how high is "high."

In Claim 4, it is not clear what the recitation “total amount of (Compound K+ginsenoside Rh1), (ginsenoside Rh1+ginsenoside Rh2), (ginsenoside Rh2+delta-20 ginsenoside Rh2+ginsenoside Rh1) or (compound K+ ginsenoside Rh1+ginsenoside Rh2) and “the amount of (ginsenoside Rc+ginsenoside Rd+ginsenoside Rb1+ginsenoside Rb2+ginsenoside Re+ginsenoside Rg1)” means. Does this mean this is a particular ginsenoside or many different ginsenosides? Why are the parentheses used? Are the groups distinct for ratio determination? Clarification is needed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6-7, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Ishida et al. (JP 63216432 A).

Ishida et al. teaches a yogurt containing ginseng, where the ginseng is pulverized and unnecessary fibers removed to provide a medicinal ginseng juice for lactic acid bacteria to carry out fermentation of the yogurt (Abstract). Yogurt inherently contain heating milk product for fermentation. Thus, milk is taught. After fermentation with lactic acid bacteria, ginseng would inherently contain Compound K, ginsenoside Rh1, ginsenoside Rh2, delta-20 ginsenoside Rh2.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ishida et al. (JP 63216432 A).

Claims 1-10 are product-by-process claims. Regarding product-by-process claims, note that MPEP § 2113 states that:

> "[w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 35 U.S.C. 102 or 35 U.S.C. 103 of the statute is appropriate…A lesser burden of proof is required to make out a case of prima facie obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. In re Brown, 59 CCPA 1063, 173 USPQ 685 (1972) ; In re Fessmann, 180 USPQ 324 (CCPA1974)… Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983). "

Ishida et al. teaches a yogurt containing ginseng, where the ginseng is pulverized and unnecessary fibers removed to provide a medicinal ginseng juice for lactic acid bacteria to carry out fermentation of the yogurt (Abstract). Yogurt inherently contain heating milk product for fermentation. Thus, milk is taught. After fermentation with lactic acid bacteria, ginseng would inherently contain Compound K, ginsenoside Rh1, ginsenoside Rh2, delta-20 ginsenoside Rh2.

The reference discloses extract which appears to be identical to the presently claimed extract, based on the fact that the both the reference extract and the claimed extract are from the same plant, are extracted in a similar manner, and have the same pharmaceutical properties. Consequently, the claimed extract appears to be anticipated by the reference.

However, even if the reference extract and the claimed extract are not one and the same and there is, in fact, no anticipation, the reference extract would, nevertheless, have rendered the claimed extract obvious to one of ordinary skill in the art at the time

the claimed invention was made in view of the clearly close relationship between the extracts as evidenced by their shared pharmaceutical characteristics.

Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 6-7, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishida et al. (JP 63216432 A) and Kim et al. (US 5776460).

Ishida et al. teaches a yogurt containing ginseng, where the ginseng is pulverized and unnecessary fibers removed to provide a medicinal ginseng juice for lactic acid

bacteria to carry out fermentation of the yogurt (Abstract). Yogurt intrinsically contain heating milk product for fermentation. Thus, milk is taught. After fermentation with lactic acid bacteria, ginseng would intrinsically contain Compound K, ginsenoside Rh1, ginsenoside Rh2, delta-20 ginsenoside Rh2. However, it does not teach treating ginseng at high temperature.

Kim et al. teaches a processed ginseng product with enhanced pharmacological effects is provided due to a heat-treatment at high temperature (Abstract). Process ginseng contain saponin components of ginsenoside Rg3, Rg5 (delta-20 gensenoside), Rh1, Rh2, Rh3, Rh4, F4 etc. (column 4, lines 21-26). Ginseng is useful in a drink composition (column 4, lines 39-44). The processed ginseng extract comprising a ratio of ginsenoside (Rg3+Rg5) to (Rc+Rd+Rb1+Rb2) above 1.0 (Claim 1).

Ishida et al. teaches a yogurt containing ginseng (Abstract) and Kim et al. teaches a processed ginseng product with enhanced pharmacological effects is provided due to a heat-treatment at high temperature (Abstract). Yogurt processing requires heating of milk. Thus, an artisan of ordinary skill would reasonably expect that heating ginseng with milk could be used as the types process to make ginseng product process by heat taught by the references. This reasonable expectation of success would motivate the artisan to use the process of Kim et al. in the reference composition. Thus, using heated ginseng extract in yogurt processing is considered an obvious modification of the references.

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Examiner Art Unit 1655

/Michael V. Meller/

Primary Examiner, Art Unit 1655